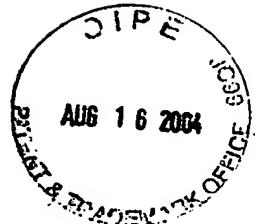


Patent Docket No.: FC0807Q1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of: McShane)
Serial No.: 09/675,938)) Examiner: S. Sharareh
Filed: 9/29/00)) Art Unit: 1617
For: Foot and Shoe Deodorant))

Commissioner, Patents
P.O. Box 1450
Alexandria, Va. 22313-1450

Appeal Brief

Sir:

This appeal is taken from the decision of the Primary Examiner, mailed on February 12, 2004, in which claims of the subject application were finally rejected. Further to the Notice of Appeal filed on May 14, 2004 this appeal brief is being provided in triplicate: one bearing an original signature and two photocopies thereof. A fee transmittal sheet is enclosed, in duplicate, for charging the appeal brief fee. Also requested is a one month extension of time and the requisite fee therefor.

1. Real Party in Interest

The real party in interest in this appeal is Schering-Plough HealthCare Products, Inc., assignee of the subject patent application by virtue of an assignment executed by the inventor/appellant.

2. Related Appeals and Interferences

There are no related appeals or interferences that would be affected by a decision in this appeal.

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3. Status of Claims

The application was filed with claims 32-42. No claims were added or deleted during prosecution. Thus, claims 32-42 are the subject of this appeal.

4. Status of Amendments

All of the appellant's amendments have been entered; there was no amendment presented after final rejection.

5. Summary of the Invention

The present invention is directed to new and un-obvious pressurized aerosol compositions for treating foot and shoe disorders, consisting essentially of a) micronized zinc oxide; b) a propellant for expelling contents of an aerosol container when pressure is released, wherein said propellant is present in an amount of about 40% to about 85%; c) about 4 to about 50 percent of a solvent selected from the group consisting of water and C₁ to C₃ alcohols, wherein said pressurized aerosol composition is for treating foot and shoe disorders.

6. Issues

The issues of this appeal can be stated as follows:

1. Is there any combination of any part of the Nakane reference that reasonably renders the appealed claims obvious?
2. Is there any combination of any part of the Lisboa and Lajoie references that reasonably renders the appealed claims obvious?
3. Are the claims indefinite?

7. Grouping of Claims

Patentability issues for individual pending claims do not appear to be substantially different. Therefore, for purposes of this appeal, the claims can be considered to stand or fall together.

8. Argument

1. Obviousness

The law concerned with claim obviousness is rather well established. Comprehensive fundamental guidance has been provided by the U.S. Supreme Court in *Graham v. John Deere*, 148 USPQ 459 (1966), which requires the following steps for making an obviousness determination:

1. Determine the scope and content of the prior art.
2. Ascertain the differences between the prior art and the applicant's claims.
3. Resolve the level of ordinary skill in the art.

From the second step, it is apparent that differences between the claimed invention and the cited prior art should be indicative of patentability over that art.

In M.P.E.P. § 706.02(j) the requirements for a proper rejection under 35 U.S.C. § 103 are discussed, including a statement attributed to *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991): "Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

With these principles in mind, the present rejection of appellants' claims is clearly erroneous. There is no combination of teachings that includes all of the limitations of any of the rejected claims.

The final rejection erroneously failed to consider the patentable effect of the appellants' claim description of their invention as a "foot and shoe deodorant," stating that the term was "being based on a future intended use and is not given patentable weight." However, that statement is not in accord with decisions that include *In re Duva*, 156 USPQ 90 (CCPA 1967), holding at page 94:

The command of 35 U.S.C. 103 is to compare the invention as a *whole* with the prior art. Absent a failure of the applicant to comply with 35 U.S.C. 112, we think every portion of the appealed claims must be considered in determining the invention as a whole in arriving at our decision as to obviousness required by a rejection under section 103.

The applicable law holds that terms in the preamble generally will not be considered as being limitations that impart novelty to a claim, but should be used to establish the limits of reference teachings that might establish obviousness. Due to the absence of teachings in the presently applied art that relate in any manner to the appellants' concededly novel claims, there can be no proper holding of obviousness.

Claims 32 to 42 were rejected under 35 USC § 103 as obvious over Nakane, *et al.*, U.S. Patent No. 5,122,418 ("Nakane"). (Office Action at p. 2). For the reasons set forth below, the rejection respectfully is traversed.

Nakane reportedly discloses a "composite" powder of an inorganic or organic core powder that is reportedly covered with one or more types of organic, inorganic or metallic powders. See, e.g., Abstract. The "composite" powder of Nakane reportedly can be used as a skin treatment agent, in make up, as a sunburn-preventing agent or as a deodorant. (*Id.*). In one embodiment of Nakane, there reportedly is disclosed a deodorant comprising a composite powder comprised of a "synthetic resin powder" and a "hydroxyapatite." (Col. 5, Ins. 15-20). Nakane further reportedly discloses that the composite powder can comprise a "metal oxide," in place of the hydroxyapatite. Nakane reportedly discloses that "the deodorant can be used in the form of, for example, aerosols, roll-ons, powders, lotions, creams, sticks, and other external deodorants, and further, shoe lining and household use type deodorants." (Col. 6, Ins. 3 to 11).

Nakane also reportedly discloses a number of examples. Examples 30 to 40 generally reportedly disclose deodorant sprays and powders. More specifically, Examples 30 and 31 reportedly disclose aerosol deodorant sprays, yet make no mention of zinc oxide. Examples 32 to 34 reportedly are powders and make no mention of zinc oxide. Example 35 reportedly discloses a deodorant spray containing the "composite" powder including zinc oxide in a 20 gram to 80 gram ratio to nylon in the composite powder and the powder is reportedly present in an amount of 1.5% of the composition. Thus, the zinc oxide reportedly is present in an amount of 0.3%. Further, the deodorant was reportedly applied under the test subject's arm. Example 36 discloses another spray reportedly containing zinc oxide present in an amount of 0.24% based on the composition of the Example. Examples 37 to 40 reportedly further disclose deodorant powders, yet only examples 37 and 38 mention zinc oxide.

In making the rejection, the Examiner stated that Nakane discloses micronized zinc oxide and a fragrance. (Office Action at p. 3). The Examiner further stated that the amount of zinc oxide used in Nakane's compositions falls within the same range as instantly claimed. (*Id.*). The Examiner further

stated that Nakane's composition also comprise a propellant as an aerosol deodorant and water and C₁ to C₃ alcohols. (*Id.*) The Office then concluded that, relying upon *Sinclair & Carroll Co., Inc. v. Interchemical Co.*, 65 U.S.P.Q. 297 (U.S. 1945), that Nakane's composition would render obvious the limitations of the instant claims. (Office Action at pp. 3-4).

A *prima facie* case of obviousness, requires that the rejection describe with specificity why one skilled in the art would have combined two references to arrive at the claimed invention. *In re Dembiczaik*, 50 U.S.P.Q.2d 1614, 1617 (CAFC 1999). ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of *the requirement for a showing of the teaching or motivation to combine prior art references.*"). The Office was required to demonstrate *where* in the reference there is a suggestion which would have "strongly motivated" one to make the formulations as claimed. *Ex parte Graselli*, 231 U.S.P.Q. 393, 394 (Bd. App. 1986). The type of motivation which would have "impelled" one to do so (*Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1301-02 (B.P.A.I. 1993)), and the type of suggestion that the changes "should" be made. *Ex parte Markowitz*, 143 U.S.P.Q. 303, 305 (Bd. App. 1964). It respectfully is submitted that the Office has not met its burden in demonstrating any suggestion or motivation to combine the various portions of Nakane to arrive at the claimed invention.

Moreover, it respectfully is submitted that the Office's reliance on the holding of *Sinclair* is misplaced. *Sinclair* is a case of a notorious era in the history of patent law where the Supreme Court took a very anti-patent stance. Indeed, as one Justice stated, albeit it in dissent:

It would not be difficult to cite many instances of patents that have been granted, improperly I think, and without adequate tests of invention by the Patent Office. But I doubt that the remedy for such Patent Office passion for granting patents is an equally strong passion in this Court for striking them down so that the only patent that is valid is one which this Court has not been able to get its hands on.

Jungersen v. Ostby & Barton Co., 335 U.S. 560 (1949) (Justice Jackson dissenting). Simply put, the case is from an era where patents were under attack. Furthermore, to the extent that the case discounted the manner in which the inventor arrived at the claimed invention in that case, that was overruled by the 1952 Patent Act ("Patentability shall not be negated by the manner in which the invention was made") and no showing of any facts as to how the present invention was arrived at has been made. And mere characterization of alleged picking and choosing so much of Nakane and the art the Examiner has asserted is not the stuff of a rejection under 35 U.S.C. § 103. Further, with regards to the Examiner's statement that it is still good law, the undersigned respectfully submits that Shepherd's is simply wrong. A fair reading of that case and a fair reading of the 1952 amendment to the Patent Statute verifies that.

Thus, for all of the foregoing reasons, it respectfully is submitted that the rejection of claims 32 to 42 over Nakane should be reversed.

2. Obviousness Rejection

Claims 32 to 42 were rejected under 35 U.S.C. § 103 (a) as being unpatentable over Lajoie, U.S. Patent No., 5,466,470 ("Lajoie"), in view of Lisboa, U.S. Patent No. 5,679,324 ("Lisboa"). (Office Action at pp. 4 to 5.). For the reasons set forth below, the rejection respectfully is traversed.

Lajoie reportedly discloses a "co-micronized" bicarbonate salt composition comprising a blend of ingredients that can include, *inter alia*, zinc oxide as one of many choices of ingredients. The Examiner alleges that Lajoie also discloses "thickeners, surfactants and fragrances" in Examples 3 and 4. Lajoie does not disclose, a fact the Examiner admits, any aerosol formulations.

Lisboa reportedly discloses "cosmetic aerosol foams" for shaving. The compositions of Lisboa may contain any number of additional ingredients. Lisboa reportedly states that zinc oxide may be present as a "sunscreen active agent." Col. 8, Ins. 11 to 21).

In making the rejection, the Examiner asserted that Lajoie teaches co-micronized bicarbonate salts and zinc oxide, in addition to thickeners, surfactants and fragrances. (Office Action at p. 4). The Examiner acknowledged, however, that Lajoie differs from the presently claimed invention in that it does not disclose a pressurized aerosol formulation. (*Id.*).

To fill the acknowledged gap, the Office relied upon Lisboa as teaching the desirability of aerosols. (*Id.*).

The Office then concluded that "it would have been obvious to one of ordinary skill in the art at the time of the invention to add a propellant, such as those taught by Lisboa, to the compositions of Lajoie and formulate an aerosol topical delivery system of Lajoie's compositions, because one of ordinary skill in the art would have had a reasonable expectation to succeed in formulating aerosolized formulations that are easy to use and more appealing to the general consumers." (*Id.* at pp.4-5).

The Examiner alleges that Lisboa "teaches propellant containing topical cosmetic or therapeutic compositions Lisboa suggests that the use of aerosol compositions gaining wide appeal among both men and women as they are easy to use." (Office Action at p. 4). However, Lisboa states in full that "cosmetic aerosol foam compositions, particularly those used in association with shaving are well known in the art. Aerosol shaving compositions such as shaving creams and shaving gels have been used for a number of years, with aerosol shaving gels recently gaining wide appeal among both men and women." (emphasis added) Col. 3, Ins. 16 to 22. Lisboa does not state some general desirability of formulations containing a propellant, but mentions aerosol shaving creams and shaving gels "gaining wide appeal among both men and women." For this reason, the rejection is not based on facts and should be withdrawn for this reason alone.

The Examiner further states that Lisboa "teaches that the use of propellants in preparing aerosol formulation containing various cosmetically suitable ingredients is conventional." The Examiner does not cite where in Lisboa this assertion is made. Applicants are left to guess what portion of the disclosure of Lisboa the Examiner is relying upon as there is no citation to any portion of Lisboa to support this assertion.

That notwithstanding, the mere assertion by Lisboa that shaving creams utilizing a propellant are "well known" is not statutory prior art. To treat Lisboa's statement, with regards to shaving cream, and then to extend it as such to foot and shoe deodorants, would render every propellant containing composition in the world as obvious. Surely Lisboa does not have such a devastating effect, let alone such an effect as statutory prior art. As the precedent above clearly establishes, an obviousness rejection must be based on facts - not generalities. For this further reason, the rejection should be withdrawn.

Moreover, to the extent the Examiner contends that the disclosure of Lisboa that the use of propellants in shaving creams is "conventional," this too does not establish a *prima facie* case of obviousness *per se*. As the Federal Circuit has stated:

[V]irtually all [inventions] are combinations of old elements. *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ('Most, if not all, inventions are combinations and mostly of old elements.'). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each element were sufficient to negate patentability, very few patents would ever issue.

In re Rouffet, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998). Thus, whether or not a claim limitation recites the use of an "old" or "conventional" element, that fact does not render the claims as obvious *per se*, and impermissibly ignores the other limitations of the claim. And, as the Examiner is no doubt aware, there are no *per se* rules of patentability. *In re Ochiai*, 37 U.S.P.Q.2d 1127 (Fed. Cir. 1995).

Aside from the factual deficiencies set forth above, it respectfully is submitted that the Office Action did not set forth a *prima facie* case of obviousness. A *prima facie* case of obviousness requires that the rejection describe with specificity why one skilled in the art would have combined two references to arrive at the claimed invention. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based

obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.".). In the present case, no such explanation is found in the rejection. The Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would "impel" one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1301-1302 (B.P.A.I. 1993).

The Examiner was required to demonstrate where in Lisboa and Lajoie there is a suggestion which would have "strongly motivated" one to make the compositions as claimed. *Ex parte Graselli*, 231 U.S.P.Q. 393, 394 (Bd. App. 1986), and the type of suggestion that the changes "should" be made. *Ex parte Markowitz*, 143 U.S.P.Q. 303, 305 (Bd. App. 1964). The rejection fails to provide any specific reason why one would be motivated, let alone impelled, to combine Lisboa with Lajoie in the manner suggested by the Examiner. Thus, the rejection fails to set forth the required facts and reasoning required to support a *prima facie* case of obviousness. Accordingly, it respectfully is submitted that the rejection of claims 32 to 42 for this basis should be withdrawn.

Moreover, the claims to require that the aerosol be an aerosol for treating foot and/or shoe odors. The rejection fails to identify where in Lajoie or Lisboa such a limitation can be found. Indeed, as is fundamental, all properties and attributes of a claimed invention must be considered by the Examiner. *In re Antonie*, 195 U.S.P.Q. 6, 8 (C.C.P.A. 1977). For this further reason, the rejection should be reversed.

Regarding the Examiner's contention that the skilled artisan would have had a reasonable expectation of success in formulating aerosolized formulations "that are easy to use and more appealing to the general consumers," applicants respectfully disagree with this contention. In order for a reference to provide a reasonable expectation of success, the references themselves must provide such an expectation in addition to the suggestion to combine. *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The applicant's own disclosure may not be the source of a reasonable expectation of success. The only facts the Examiner pointed to was a statement in the

"background" of the invention of Lisboa that aerosol foam compositions are well known, and some general conclusion that there is a need for formulations that "are easy to use and are more appealing to the general consumers." This standard for a reasonable expectation of success or a motivation to combine is not found in either of the references, and is thus not of record, and is contrary to the law of obviousness. "Ease of use" and "appeal" to consumers is no substitute for a disclosure in the art that one would have had a reasonable expectation of success in formulating the aerosol formulations containing the particular ingredients recited in the claims of the present invention.

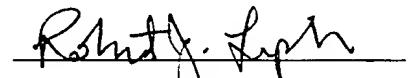
3. Indefiniteness

The Examiner newly rejected claims 32 to 42 because the defendant claims were allegedly broader than the independent claim. That contention is incorrect. By their very nature, they can not be broader than the independent claim.

CONCLUSION

In the absence of any reasonable basis to make out a case for obviousness, reversal of the improper final rejection under 35 U.S.C. § 103 (a) and 35 U.S.C. § 112 (2) of appellant's claims 32-43 is appropriate, and such action is respectfully solicited.

Respectfully submitted,



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APPENDIX - CLAIMS ON APPEAL

Claims 1-31 (cancelled)

32. (new) A pressurized aerosol composition for treating foot and shoe disorders, consisting essentially of

- a) micronized zinc oxide;
- b) a propellant for expelling contents of an aerosol container when pressure is released, wherein said propellant is present in an amount of about 40% to about 85%;
- c) about 4 to about 50 percent of a solvent selected from the group consisting of water and C₁ to C₃ alcohols, wherein said pressurized aerosol composition is for treating foot and shoe disorders.

33. (new) The composition according to claim 32 further comprising a fragrance to help mask any foot odors and/or provide a more pleasant odor to the foot or shoe.

34. (new) The composition according to claim 32 further comprising a thickening agent capable of thickening the contents of the aerosol.

35. (new) The composition according to claim 32 further comprising a base to neutralize any organic or inorganic acids.

36. (new) The composition according to claim 32, wherein the amount of micronized zinc oxide in the aerosol is in the range of from about 0.5% to about 15% by weight.

37. (new) The composition according to claim 36, wherein the amount of micronized zinc oxide in the aerosol is in the range of from about 2% to about 12% by weight.

38. (new) The composition according to claim 37, wherein the amount of micronized zinc oxide in the aerosol is in the range of from about 3% to about 10% by weight.

39. (new) The composition according to claim 32, wherein the average particle size of the zinc oxide is in the range from about 26 to about 46 nanometers.

40. (new) The composition according to claim 33, wherein the average particle size of the zinc oxide is in the range from about 30 to about 40 nanometers.

41. (new) The composition according to claim 40, wherein the average particle size of the zinc oxide is in the range from about 35 to about 37 nanometers.

42. (new) A method of inhibiting foot or shoe odor comprising administering to a foot or shoe the Composition of claim 32.